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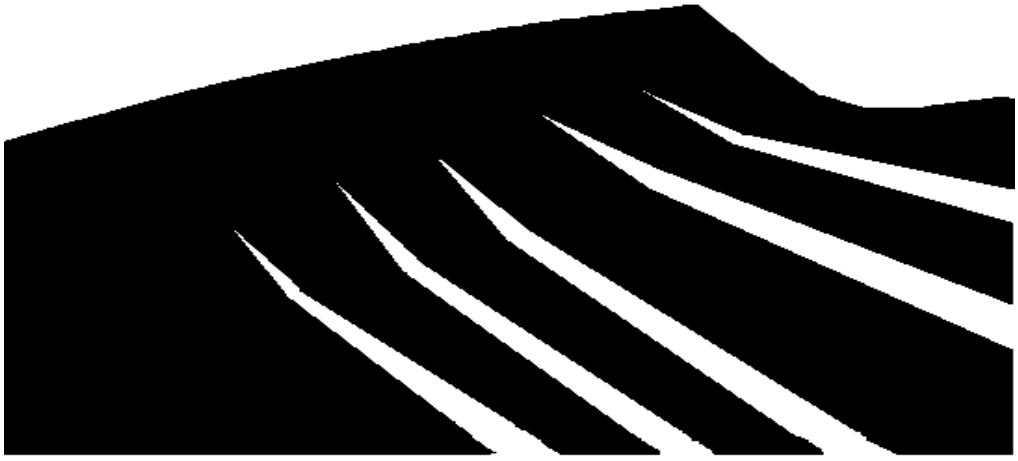
DOCUMENTING SCIENTIFIC INVESTIGATIONS

LOS ALAMOS

QUALITY PROGRAM



APPROVAL FOR RELEASE

J. T. FABRYKA-MARTIN - PREPARER Signature on file	DATE Date on file
M. J. CLEVENGER - QUALITY ASSURANCE PROJECT LEADER Signature on file	DATE Date on file
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Los Alamos
Yucca Mountain Site Characterization Project

HISTORY OF REVISION

REVISION NO.	EFFECTIVE DATE	PAGES REVISED	REASON FOR CHANGE
R0	03/10/92	N/A	Initial procedure.
R1	12/07/92	All	Complete rewrite to simplify process.
R2	01/31/94	All	Complete rewrite to address new QARD requirements and to simplify process.
R3	08/01/94	All	Address QARD requirements and RTN review comments.
R4	11/03/94	3, 5-8, Atts. 2 & 3	Revised in response to CAR YM-94-081.
R5	09/05/95	3, 4, 7, & Att. 1	Minor, non-substantive editorial changes to clarify the data submittal process.
R6	08/08/96	All	Address revised QARD requirements and to clarify the data submittal process.
R7	11/05/96	6	Minor, non-substantive change in response to DOE audit concern. Added name and version of software requirement to subsection 6.1.7.3.
R8	06/02/97	9-10	To change quality assurance staff responsibilities to technical assurance staff responsibilities.

DOCUMENTING SCIENTIFIC INVESTIGATIONS

1.0 PURPOSE

This procedure describes the process for documenting scientific investigations for the Los Alamos National Laboratory (Los Alamos) Yucca Mountain Site Characterization Project (YMP or Project).

2.0 SCOPE

2.1 This procedure governs the documentation of Los Alamos YMP scientific investigations.

2.2 QP-02.12 requires Laboratory Lead (LL) approval to take exemption from quality assurance requirements for prototype or scoping activities at the Planning and Control Systems (PACS) summary account level. If QP-02.12 is utilized, the Exemption Justification reference number will be referenced in the laboratory notebook. However, it is recognized that a Principal Investigator (PI) may require the flexibility for prototype or scoping work within a summary account. In such cases, an initial entry will clearly identify the work as prototype or scoping, e.g., "The following entry documents the work as prototype or scoping activity, and data are not to be used for licensing," or a similar statement. These entries may be documented in the same notebook that is used to record quality-affecting work.

2.3 This procedure applies to Los Alamos and Los Alamos subcontractor YMP personnel (hereafter referred to as YMP personnel) who work under the Los Alamos YMP quality assurance program.

3.0 REFERENCES

LANL-YMP-QP-02.12, Exemption Control
LANL-YMP-QP-03.21, Software Life Cycle
LANL-YMP-QP-08.3, Transfer of Data
LANL-YMP-QP-12.3, Control of Measuring and Test Equipment and Standards
LANL-YMP-QP-17.6, Records Management

4.0 DEFINITIONS

4.1 Commercial or Government-off-the-shelf Software Packages

Software packages that are exempt from qualification (see subsection 6.1.7.3) are as follows: spreadsheets such as EXCEL and Lotus 1-2-3, Microsoft Access, FoxPro, database managers such as dBase, operating systems such as DOS and Windows, administrative and management systems, system compilers, utilities, and associated libraries, word processing programs such as WORD and WordPerfect, graphing and visual display software, statistical analysis programs, or software included with test or data gathering equipment.

4.2 Scientific Investigation

A scientific investigation is any observation, identification, description, experimental study, or analysis and explanation of natural phenomena (e.g., research and development and field activities).

4.3 Scientific Notebook

A scientific notebook (hereafter referred to as a notebook) is a record of the methodology and results of scientific investigations. Three types of notebooks are used on the Los Alamos YMP, but these need not be mutually exclusive. A single notebook may contain both field as well as laboratory data; conversely, a single notebook may also contain information on miscellaneous activities (e.g., documented phone conversations).

4.3.1 Laboratory Notebook

A laboratory notebook is generally used to record activities performed in the laboratory or to compile laboratory data.

4.3.2 Field Notebook

A field notebook is generally used to record activities performed in the field or to compile field data.

4.3.3 Log Notebook

A log notebook is generally used to record tabulated data (e.g., history of calibrations, sample tracking, numerical data, or other technical data).

5.0 RESPONSIBILITIES

The following personnel are responsible for activities identified in Section 6.0 of this procedure.

- YMP personnel who document work in a scientific notebook.

6.0 PROCEDURE

The use of this procedure must be controlled as follows:

- If this procedure cannot be implemented as written, Los Alamos YMP personnel should notify appropriate supervision. If it is determined that a portion of the work cannot be accomplished as described in this QP, or would result in an undesirable situation, that portion of the work will be stopped and not resumed until this procedure is modified or replaced by a new document that reflects the current work.

- YMP personnel may use copies of this procedure printed from the controlled document electronic file; however, YMP personnel are responsible for assuring that the correct revision of this procedure is used.

- When this procedure becomes obsolete or superseded, it must be destroyed or marked “superseded” to ensure that this document is not used to perform work.

6.1 Notebook Entries

YMP personnel are responsible for the following:

6.1.1 Entries are made with photo-copyable ink (preferably black).

6.1.2 Prior to submittal as a record, notebook pages are numbered sequentially using alpha or numerical characters or a combination of the two if the notebook is subdivided.

6.1.3 Notebooks contain the following information on the first numbered page.

6.1.3.1 A primary record identifier (following the format in QP-17.6).

6.1.3.2 Name of YMP personnel responsible for the notebook.

6.1.3.3 Statement of objective and a description of the work to be performed; or, reference to an implementing document or approved study plan(s) that addresses the objective and a description of the work. The referenced study plan will include the title of the activity or activities described within that study plan.

6.1.4 Prior to submittal as a record, each notebook will contain a table of contents or an index that lists the following information:

6.1.4.1 The major sections of the notebook, and the associated page numbers.

6.1.4.2 Any applicable attachments to the notebook, (e.g., Attachment 1, 22 pages)

NOTE: Care should be taken to leave the necessary number of pages blank to complete the table of contents or the index.

6.1.5 For work governed by a Los Alamos YMP detailed technical procedure (DP), the notebook will contain the following:

6.1.5.1 Identification number and revision of the applicable DP (e.g., LANL-CST-DP-35, R3).

6.1.5.2 Information required by the DP.

6.1.5.3 Information required by Attachment 1 or Attachment 4 if measuring and test equipment (M&TE) or standards are used.

NOTE: The information in subsection 6.1.5 may be recorded in one section of the notebook instead of at each entry; however, if more than one DP governs entries in a single notebook, the entries will be traceable to the governing DP.

6.1.6 For each different research and development activity that is not covered by a DP or for which the governing DP is inadequate, the initial entry for that research and development activity contains the appropriate information listed on Attachment 2 with "N/A" entered after each item that does not apply to the activity. Any changes to the initial research and development entry are updated as appropriate and are referenced in the table of contents or index.

6.1.7 The use of software for scientific investigation is documented as follows:

6.1.7.1 Software used for prototype, scoping, or activities that are not subject to the requirements of the quality assurance program is documented as described in subsection 2.2 of this procedure.

6.1.7.2 If developed or modified software is used for scientific investigation that is subject to the requirements of the quality assurance program, the following information is recorded:

- The name and version of the software.
- The Software Transmittal (ST) (ref. QP-03.21) that allowed the use of the software.
- The name of the input and output files, if any.
- The specific constraints of the format or the setup, if any.
- Confirmation that the hardware and the input characteristics are within the described environment of the Verification and Validation Report (VVR) according to QP-03.21. If the input characteristics are outside the VVR, the software will not be used without further validation in accordance with QP-03.21.

6.1.7.3 Commercial or government-off-the-shelve software packages are exempt from qualification, under the provisions of QP-03.21, even when quality affecting formulas (or user developed macros) are included in field or cells for calculations. The formulas (or user developed macros) themselves will be documented, verified and validated (for example by peer review) if used to support quality affecting work. A list of the formulas or macros and the software name and version (e.g., EXCEL 4.0 or Microsoft Access 2.0) are to be included in the notebook describing quality affecting work to the extent necessary to enable a person knowledgeable in the subject to repeat the work using the information provided in the notebook.

6.1.8 Each entry also contains the following information:

6.1.8.1 A description of the work performed and results obtained in sufficient detail such that another similarly qualified individual could repeat the work described and achieve comparable results without consultation with the YMP personnel who made the entry.

6.1.8.2 Signature or initials of the YMP personnel making the entry (including electronic entry) and the date. This is done at the end of each day that entries are entered in the notebook.

6.2 Notebook Attachments

YMP personnel are responsible for the following:

6.2.1 Attachments (e.g., maps, charts, graphs, computer printouts, data binders, optical disk, or electronic media) will be identified and traceable to the notebook. The preferred method to identify an attachment is to record the notebook number, attachment number and the page number (sequential), and total pages on each page of the attachment. As a minimum, notebook attachments are noted in the Table of Contents or index of the notebook and the attachment labeled as follows:

6.2.1.1 The notebook number and the attachment number on the first page of the attachment.

6.2.1.2 Prior to submittal as a record, the total number of pages is noted on the first page of the attachment and in the notebook Table of Contents or index.

6.3 Notebook Data Evaluation

YMP personnel are responsible for the following:

6.3.1 Reviews and ensures completeness of data values contained in the notebook. All values other than those from prototype or scoping activities are acceptable unless explicitly rejected.

6.3.2 Rejected data will be identified such as:

Enter “Rejected Data” next to data that have been identified as unacceptable, followed by a signature or initials and date.

OR

Enter a statement in the notebook that identifies the unacceptable data and provide an explanation for rejection, followed by a signature or initials and date.

The **PI** is responsible for the following:

6.3.3 If the PI has reason to believe that data may be suspect or have been compromised because of equipment malfunction (e.g., M&TE accuracy) or failure during routine daily analysis or experimentation, the responsible **PI** ensures that the data are evaluated by a qualified individual. Rejected data are labeled in accordance with subsection 6.3.2.

6.3.4 If data are suspect because M&TE or standards are lost, out of calibration, or could not be calibrated, the **PI** conducts an evaluation according to QP-12.3.

6.3.5 Any data that have been assigned a Data Tracking Number (DTN), and are later found to be in error, superseded by more accurate data, or supplemented with additional data, are updated in accordance with QP-08.3.

NOTE: It is recommended that when a Los Alamos DTN is assigned to data in a notebook, pursuant to QP-08.3, the DTN be recorded on the applicable pages in the notebook.

6.3.6 If unqualified data are used in scientific investigation, the **PI** ensures that the data are identified as unqualified data each time they are used.

6.4 Technical Review of Notebooks

YMP personnel perform the following:

6.4.1 Ensures that a technical review is performed on a notebook and its attachments and/or data, as applicable, annually, when a notebook is closed out, or when the activity or activities terminates, which ever occurs first.

NOTE: Because it may be time-consuming to conduct a technical notebook review annually, YMP personnel are encouraged to do this quarterly. An in-process record package should be maintained to reduce the risk of losing the notebook contents.

6.4.2 Selects a technical reviewer who has the following qualifications:

6.4.2.1 The expertise necessary to understand the reviewed work.

6.4.2.2 Did not perform the reviewed work.

6.4.2.3 Trained in accordance with subsection 8.2 of this procedure.

NOTE: The technical reviewer may be the PI or a person supervising the activity, provided the above requirements are met.

6.4.3 Has a technical review performed to assure that notebook entries meet the following criteria:

6.4.3.1 Sufficient detail is provided such that another similarly qualified individual could retrace the investigation and confirm the results, if feasible, or could repeat the investigation and achieve comparable results without recourse to the investigator.

6.4.3.2 The software used is applicable to the investigation performed and the input parameters and assumptions are documented and valid.

6.4.3.3 Information in the notebook is applicable to the notebook activity listed in the notebook according to subsection 6.1.3.

6.4.3.4 Entries are correct, accurate, technically adequate, and complete.

6.4.4 Corrects each entry that does not meet the above requirements.

6.4.5 Ensures that the technical reviewer enters a statement, such as the following, on the notebook page after the last entry reviewed or in a section designated for review. “I have reviewed the entries on pages (*) through (*) and they meet the requirements described in subsection 6.4.3 and 6.4.4 of QP-03.5. All review comments noted have been corrected and/or resolved,” followed by the reviewer’s signature and date.

* Enter page numbers

6.5 Technical Assurance Review of Notebook

YMP personnel perform the following:

6.5.1 After the last technical review of a notebook is completed, a technical assurance review is performed on the notebook, including its attachments and/or data, if applicable, to ensure the following conditions are met.

6.5.1.1 The entries are legible and the configuration of the notebook meets the requirements of this procedure.

6.5.1.2 Technical reviews were performed and documented according to subsection 6.4.5.

NOTE: YMP personnel may have the review performed by the group’s Technical Assurance Liaison or may contact the Technical Assurance Project Leader (TAPL) for assignment of the review. It is recommended that a technical assurance review be performed after each technical review.

6.5.2 Corrections are made for each entry that do not meet the requirements stated in subsection 6.5.1.

6.5.3 Ensures that the technical assurance reviewer enter a statement, such as the following, on the notebook page after the last entry reviewed or in a section designated for review, "I have reviewed the entries on pages (*) through (*) and they meet the requirements described in subsections 6.5.1 and 6.5.2 of QP-03.5. All review comments noted have been corrected and/or resolved," followed by the reviewer's signature and date.

* Enter page numbers

6.6 After the last review of the notebook has been performed, transmits a copy of the notebook to a YMP Records Processing Center in accordance with QP-17.6. The transmittal should be within 90 working days of the final technical assurance review.

7.0 RECORDS

7.1 The following records resulting from this procedure are transmitted as a record package to a Los Alamos Records Coordinator in accordance with QP-17.6.

- A copy of the completed and reviewed notebook.
- Copies of notebook attachments and/or data, as applicable.

7.2 The Notebook Reviewer Qualification (Attachment 3), if applicable, is sent to the Training Coordinator as a privileged record for retention and processing in accordance with QP-17.6.

8.0 TRAINING REQUIREMENTS

8.1 Prior to conducting work described in Section 6.0, YMP personnel who document work in a scientific notebook, the responsible PI, and Technical Assurance (TA) reviewers require training to this procedure. Training is accomplished by "read only."

8.2 Technical reviewers either train to this procedure in accordance with subsection 8.1, or read, sign, and date the "Reviewer's Instructions" on the Notebook Reviewer Qualification (Attachment 3).

9.0 ATTACHMENTS

Attachment 1: Entries for Measuring and Test Equipment (M&TE) (2 pages)
Attachment 2: Entries for Research and Development and Field Activities (2 pages)
Attachment 3: Notebook Reviewer Qualifications (1 page)
Attachment 4: Entries for Consumable Standards (2 pages)

ENTRIES FOR MEASURING AND TEST EQUIPMENT (M&TE)

1. USED IN A ONE-TIME-ONLY APPLICATION

M&TE used in a one-time-only application will be calibrated before and after use. If the M&TE becomes inoperable, or its accuracy is suspected, or it is out of calibration, the user notifies the responsible PI. When performing calibrations, the following information will be recorded:

- Identification of the M&TE calibrated.
- Identification of the standard used for calibration (use the ID number shown on the applicable M&TE Report prepared in accordance with QP-12.3 or document in accordance with the requirements for Consumable Standards per Attachment 4 of this procedure).
- Procedure used.
- Calibration data.
- Calibrator's name.
- Date of calibration.
- Results of calibration and a statement of acceptability.
- Reference to any action taken in connection with out-of-calibration condition, including the evaluation of the results, as applicable.

2. CALIBRATED AT EACH USE

M&TE controlled according to QP-12.3 as calibrated at each use will have the following information recorded:

- Identification of the M&TE calibrated (use the ID number shown on the applicable M&TE Report prepared in accordance with QP-12.3).
- Identification of the standard used for calibration (use the ID number shown on the applicable M&TE Report prepared in accordance with QP-12.3).
- Identification of the Detailed Technical Procedure (including the revision level) or the notebook and page number of the procedure used in performing the calibration.
- Calibration data.
- Calibrator’s Name

- Date of calibration.

- Results of calibration and statement of acceptability.

- Reference to any action taken with respect to out-of-calibration or nonconforming M&TE including evaluation of results for acceptability.

3. CALIBRATED ON A SET FREQUENCY

- Identification of the M&TE being used (use the ID number shown on the applicable M&TE Report, or the ID number shown on the M&TE label if different from that on the M&TE Report).

- The calibration due date.

ENTRIES FOR RESEARCH AND DEVELOPMENT AND FIELD ACTIVITIES

A. DESCRIPTION

Enter the statement, "This is an R&D entry," and describe the proposed work, or reference the study plan, other planning documents, or implementing documents that describe the work to be done. The description may include reference to other notebooks, manuals, texts, etc. For field investigations describe the location where the field activities are to take place, or make reference to a map or photograph that shows the location of the site.

B. METHODS AND OBJECTIVES

State the methods to be employed and objectives of the work. Changes to methods will be documented.

C. EQUIPMENT

List any major equipment and any special materials to be used. Special materials include items such as specific reagent chemicals or specific labware (e.g., Pyrex instead of plastic). Common laboratory and field equipment does not need to be identified.

D. MEASURING AND TEST EQUIPMENT (M&TE)

Identify M&TE and Consumable Standards in accordance with the applicable requirements in attachment 1 or attachment 4.

E. SET UP REQUIREMENTS

Identify setup procedures. These may include characterization of starting materials; provisions for ensuring that experimental prerequisites are met; special measures to be taken in handling, shipping, and storing equipment; and required controlled environmental conditions.

F. SAMPLES COLLECTED OR UTILIZED

Identify samples by unique identification number.

G. ACCEPTANCE CRITERIA

Identify required levels of precision or accuracy, as applicable. Acceptance criteria may be qualitative or quantitative.

H. SOURCES OF ERROR

Identify potential sources of error or uncertainty that will be measured or controlled that could affect the results or conclusions. Identify any suspected conditions that may adversely affect the results.

I. CONCLUSIONS

At the conclusion of the work, state conclusions or observations, addressing whether the original referenced objectives as stated in the initial entry (reference notebook page entry) were achieved. Incorporate deviations from the original approach into the discussion.

NOTEBOOK REVIEWER QUALIFICATIONS

REVIEWER: _____ PHONE: _____
Print name

ADDRESS: _____

REVIEWER'S QUALIFICATIONS:

REVIEWER'S INSTRUCTIONS:

1. Ensure that the notebook entries meet the following requirements:
   a. Sufficient detail is provided such that another similarly qualified individual could repeat the work described and achieve comparable results without recourse to the original investigator.
   b. The software used is applicable to the problem being solved, and input parameters and assumptions are documented and valid.
   c. Information is applicable to the notebook activity that is listed on the first numbered page of the notebook.
   d. Entries are correct, accurate, technically adequate, and complete.
2. Have YMP personnel correct any entries that do not meet the requirements listed in Item 1 above.
3. Enter a statement in the notebook such as the following, "I have reviewed the entries on pages (*) through (*) and they meet the requirements described in Step 1 of the reviewer's instructions of this form. All review comments noted have been corrected and/or resolved."

   * Enter page numbers
4. Sign and date the notebook and this form, and return them to the employee.

I HAVE READ AND UNDERSTOOD THE ABOVE INSTRUCTIONS.

REVIEWER'S SIGNATURE: _____ _____
Date

YMP PERSONNEL APPROVAL:

NAME: _____ _____ _____
Print name Signature Date

THIS FORM IS PRIVILEGED INFORMATION. FORWARD TO TRAINING COORDINATOR, MS M321

Los Alamos
Yucca Mountain Site Characterization Project

ENTRIES FOR CONSUMABLE STANDARDS

The following information for each consumable standard, as applicable, is documented in a notebook or logbook.

1. Identifier

- Will be unique, e.g.,
  - *lot number for chemical*
  - *purchase request number*
  - *alphanumeric identifier using date*

2. Description

- Physical Form, e.g.,
  - *solid, powder*
  - *gas*
- Chemical formula, if applicable, e.g.,
  - *sodium chloride*

3. Supplier or Source, e.g.,

- National Institute for Standards and Technology (NIST).
- Baker Chemical Company.
- Produced by the PI.

4. Date Received

5. Storage Location, e.g.,

- Subcontractor's name, city, and state.
- LANL
  - *Technical Area*
  - *Building and room*

6. Designated Usage on Los Alamos YMP, e.g.,

- For calibration of a pH meter or ion chromatography system.
- Submission as a blind sample to provide quality check of results from outside analytical laboratories.

7. Certified Value and its Uncertainty

8. Certification Information

- Certificate showing accuracy and tolerance or stated physical or chemical value, and tractability to NIST or other nationally recognized standard.
- If standard is not traceable to NIST or equivalent, describe the basis for using the standard, e.g.,
  - *Published reports or articles as basis for certification (e.g., Geostandards)*

9. Special Handling and Storage Instructions, e.g., for solutions:

- Tightly capped.
- Refrigerated.

10. Expiration Date

11. Assigned Custodian

12. PI's Name

13. Documentation of Usage (i.e., where and how is documentation kept), e.g.,

- Logbooks associated with M&TE that are controlled by QP-12.3.
- Logbook maintained by YMP personnel specifically for documenting the use of standards.

14. Date the Standard was Removed from Los Alamos YMP Control System

15. Reason for Removal from Los Alamos YMP Control System, e.g.,

- Expiration date arrived
- Used up
- Found to be in error

16. If the standard is removed for reasons other than the standard was consumed or the expiration date has been exceeded the PI's approval (e.g., signature and date) authorizing the removal from Los Alamos YMP Control System is required.